



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,010	01/22/2004	Eugene J. Alexander	6750-0007.02 SU98-U01.US1	8938
36806	7590	09/06/2007	EXAMINER	
Imaging Therapeutics, Inc c/o Bromberg & Sunstein LLP 125 Summer Street BOSTON, MA 02110-1618			CWERN, JONATHAN	
			ART UNIT	PAPER NUMBER
			3737	
			MAIL DATE	DELIVERY MODE
			09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/764,010

Applicant(s)

ALEXANDER ET AL.

Examiner

Jonathan G. Cwern

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of copending Application No. 09/953373. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. Claims 1-33 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-140 of prior U.S. Patent No. 7239908 (Application No. 09/662,224). This is a double patenting rejection.

Claim Objections

1. Claims 30 and 31 are objected to because of the following informalities: in claim 30, reference is made to "steps (a) through (b)". Steps (a) through (b) are not found anywhere in claim 26. For purposes of examination, examiner interprets steps (a) through (b) to simply be the content of claim 26, obtaining a 3-d map being step (a) and

Art Unit: 3737

determining the margins of the diseased cartilage being step (b). Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5, 7, 8, 10, 11, 13, 15, 16, 23, 24, and 26-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (US 5320102).

Paul show in the figures and text, pertaining to claims 1-3, 5, 7, 8, 10, 11, 13, 15, 16, 23, 24, and 26-33, a method of treating a human with diseased cartilage in a joint (abstract), which method comprises: utilizing an MRI scan to generate a cross-sectional electronic image of said joint (column 4, lines 1-55), wherein said image includes both normal and diseased cartilage (column 10, lines 55-65); and utilizing information from said image to create a geometric model of an area of diseased cartilage (the MR cartilage image is a model, column 4, lines 55-65), wherein said geometric model is used in selecting a treatment of said diseased cartilage (column 11, lines 35-55); electronically evaluating the image of the joint to determine the thickness or biochemical content (column 4, lines 1-10, and column 5, line 65-column 6, line 5); obtaining a three-dimensional map (the MR cartilage image is a three-dimensional map, column 4, lines 55-65); determining the margins of the diseased cartilage in relation to the normal cartilage based on the thickness or biochemical contents, allowing for the area of

Art Unit: 3737

diseased cartilage to be calculated (the MRI scan of the joint allows for the total cartilage surface area to be determined, knowledge of the margins of the diseased area will then allow for a calculation of the total area of the joint containing diseased cartilage, column 10, lines 55-65). Also, estimating the change in thickness of a region of the cartilage over time to determine a change in thickness between a first time and a second time, to determine the amount of degeneration in the cartilage (column 11, lines 5-55); the therapy includes an agent that stimulates repair of diseased tissue (column 11, lines 45-55); the MRI technique obtains a series of two-dimensional views reconstructed to a three-dimensional image (implicit with MR imaging); the MRI technique employs gradient or spin echo (column 4, lines 25-40).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4, 6, 9, 12, 14, 17-19, 21-22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aouni-Ateshian et al. (US 6161080) and further in view of Goldberg et al. (US 6835377).

Paul show the invention substantially, in the preceding rejection under 35 USC 102(b).

Paul fail to show, with respect to claims 4, 6, 9, 12, 14, 17-19, 21-22, and 25, the therapy comprises osteotomy or an autologous chondrocyte transplantation; the information is used to determine a geometrical feature of a tissue replacement material or scaffold; the physical model is used to shape a tissue replacement material; the physical model is implanted into a knee joint.

Aouni-Ateshian teach, with respect to claims 4, 6, 9, 12, 14, 17-19, 21-22, and 25, generating a 3D computer model of a knee joint (figures and column 2, line 1); obtaining geometric data specific to the patient to generate the model, the data coming from MR imaging (column 38); and using the computer model to design a prostheses and other medical instruments (column 1, lines 55-65).

Goldberg teach, with respect to claims 4, 6, 9, 12, 14, 17-19, 21-22, and 25, the therapy comprises osteotomy or an autologous chondrocyte transplantation (it is well known to perform osteotomy, column 1, lines 40-50, also the method used in the invention uses autologous mesenchymal stem cells supported by a three-dimensional scaffold, which is implanted in the body, column 3, lines 1-25).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have combined the implant taught by Goldberg, with the 3D

Art Unit: 3737

modeling techniques taught by Aouni-Ateshian, with the degenerative cartilage diagnosis and treatment methods taught by Paul, with the motivation that implanting a scaffold containing stem cells is a well known method for provide healing in a human joint. There is a reasonable expectation of success to combine these references because Paul teach diagnosing and treating degenerative cartilage, although their treatment involves using drugs or other agents. However other treatment methods could be used. Goldberg teach a treatment method involving an implant, although they do not mention how the implant is created. Aouni-Ateshian teach a 3D computer model that can be created from MRI data taught by Paul, and the model can be used to design an implant such as taught by Goldberg.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aouni-Ateshian et al. (US 6161080) and further in view of Goldberg et al. (US 6835377) and further in view of George, III et al. (US 6175655).

Paul, Aouni-Ateshian, and Goldberg show the invention substantially, in the preceding rejections under 35 USC 102(b) and 35 USC 103(a).

Paul, Aouni-Ateshian, and Goldberg fail to show, with respect to claim 20, that the model is created with a 3D Euclidean distance transformation.

George, III teach, with respect to claim 20, a method for manipulating 3D MRI data to view internal body structure (abstract), use of 3D Euclidean distance values in manipulating the 3D MRI data (table of column 8-column 9 shows a variable used which is Euclidean distance between points).

It would have been obvious to one of ordinary skill in the art, to have used Euclidean distance values as taught by George, in the combined method of Paul, Aouni-Ateshian, and George, with the motivation that using Euclidean distance is well known in calculating the distance between two points. The distance between points is used when constructing the 3D model.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached Notices of References Cited Sheet.

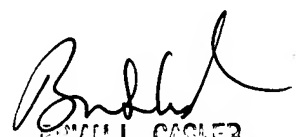
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is 571-270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
8/29/07


BRIAN L. CAGLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER